

REMARKS

Reconsideration of the above-captioned application is requested.

Claims 1 and 5 have been amended to more clearly distinguish over the prior art; new claims 18 and 19 have been added; and claims 7-17 have been cancelled.

The present invention relates to a retrograde cannula for delivering fluid to a patient's vessel, e.g., delivering cardioplegia to a patient's heart. The cannula body includes an infusion lumen 16 for conducting the fluid to a lumen outlet 20. An automatically inflatable balloon 12 is provided, and arranged via passage 30, to be inflated by the fluid that is being conducted through the infusion lumen. In order to keep the balloon in an inflated state when the delivery of cardioplegia is halted, a valve is provided, e.g., the slideable valve 34 of Figs. 1 and 2, or the flexible sleeve 50 of Figs. 3 and 4, which can be moved from an open position to a closed position in which the passage 30 is closed. Thus, the balloon, and with it the cannula, is held in place in the patient's body even when no fluid is being administered. Hence, there is no need to reinsert or reposition the cannula in order to administer a second dose of fluid. Fluid communication between the lumen inlet and the lumen outlet is maintained regardless of whether the valve is open or closed.

Claims 1 and 5 have been rejected as anticipated by any of: *van Erp*, *Bromander*, *Dye et al.* and *Briscoe*.

van Erp

Van Erp discloses a balloon catheter having passages 14 (i.e., the left-hand passages 14 in Figs. 2-4) for communicating a balloon 3 with an infusion lumen 2. Also disclosed are a number of valves 9, 11, 15 for controlling fluid flow within the catheter. Of those valves, only the valve 11 is able to open/close those passages 14. That valve 11 can be moved from an open state (Fig. 2) in which the balloon is being inflated by fluid conducted through the passages 14 to a closed state (Fig. 4) in which the passages 14 are closed to maintain pressure inside the balloon.

Each of present claims 1 and 5 recites, *inter alia*, a "passage arrangement for fluidly communicating the balloon with the infusion lumen." It will be appreciated that such a passage arrangement corresponds to the passage(s) 14 in van Erp.

Claim 1 further recites a valve arranged in the body for being shifted between an open position to open the passage arrangement, and a closed position for closing the passage arrangement. It will be appreciated that in van Erp constitutes the sole valve for opening/closing the valve 11. (The valve 15 of van Erp can close the infusion lumen 2, but cannot close the passage arrangement 14 communicating the balloon with the infusion lumen).

Claim 1 further recites:

"the valve arranged to maintain fluid communication between the lumen inlet and the lumen outlet arrangement while in its open position and its closed position."

That feature is not found in van Erp, because in van Erp, when the valve 11 is in a passage-closing position, all communication between the lumen inlet 16 and the lumen outlet (i.e., the right-hand-most passages 14 in Figs. 2-4) is blocked (not "maintained" as claimed). Accordingly, it is submitted that claim 1, as written prior to this response, distinguishes patentably over van Erp. However, just to make certain that claim 1 is not misinterpreted, the last paragraph of the claim has been amended to repeat the fact that the valve can communicate the balloon with the infusion lumen, or block such communication -- only the valve 11 of van Erp performs that function.

Claim 5 distinguishes patentably over van Erp for the same reasons as claim 1, the difference being that claim 5 employs the expression "passage opening and closing means" instead of "valve".

Bromander

Bromander does not disclose a retrograde cannula for delivering fluid to a patient's vessel as presently claimed, but rather discloses a balloon dilation catheter for dilating a body vessel. That is, Bromander's balloon is inflated and then forced through a vessel to dilate the vessel. Thus, the *Bromander* catheter does not disclose an infusion lumen having an outlet arrangement for discharging fluid from the infusion lumen to a patient's vessel, as recited in claims 1 and 5.

Bromander's dilation catheter includes a guide wire lumen 12 which is adapted to conduct balloon-inflating fluid while the distal end of the lumen 12 is blocked by a plug 46, as shown in Figs. 2 and 5 and described at column 6, first paragraph. After the balloon has been inflated, the plug is removed to enable a guide wire to be inserted through the catheter. Therefore, while *Bromander's* catheter includes a passage arrangement for fluidly communicating the balloon with the lumen 12, that passage arrangement does not enable the balloon to be inflated by pressurized fluid which is being conducted through the infusion lumen and through the lumen outlet as recited in claims 1 and 5. At no time does a balloon inflating fluid flow enter a patient's vessel when using *Bromander's* dilation catheter.

Accordingly, it is submitted that claims 1 and 5 distinguish patentably over Bromander.

Dye et al.

Dye et al. does not disclose a retrograde cannula for delivering fluid to a patient's vessel, as recited in claims 1 and 5, but rather relates to a drainage catheter for draining fluid from a patient. That difference leads to important structural differences between Dye et al. and the presently claimed invention. That is, in Dye et al. nowhere is there an infusion lumen having outlet arrangement for discharging fluid from the infusion lumen to a patient's vessel. In fact, Dye et al. take specific measures to prevent the discharge of any fluid from the catheter to the patient, in direct contrast to the presently claimed invention. In Dye et al., fluid

introduced into the proximal end of the catheter is used solely for inflating the balloon; it is not discharged into the patient. In the embodiments according to Figs. 1-4 and 11-12, an inflation lumen 32 or 32d is provided which is separate from the drainage lumen. However, the lumen outlet 38 only leads to the balloon, not the patient's vessel.

In the remaining embodiments of Dye et al., the drainage lumen 28 or 28a doubles as an inflation lumen, but a one-way valve 70 is provided at the lumen outlet to prevent, not permit, the discharge of fluid from the lumen to the patient's vessel.

In conclusion, nowhere in any of the embodiments of Dye et al. is there a lumen having an outlet arrangement for discharging fluid from the lumen to a patient's vessel, nor would there by any reasons to provide such in a drainage catheter.

Accordingly, it is submitted that claims 1 and 5 distinguish patentably over Dye et al. Note also new dependent claims 18 and 19 which recite that the lumen outlet is non-valved, in contrast to the valve 70 used in Dye et al. to close the outlet of the lumen.

Briscoe

Claims 1 and 5 stand rejected over Fig. 8 of Briscoe, in which a stylet 46 is inserted into a catheter to stiffen the catheter for entry into a patient's body. The stylet 46 includes a plug 70 at its distal end which prevents a backflow of fluid into the catheter from a patient's body as the catheter is being inserted (i.e., premature inflation of the balloon is prevented by fluid from the patient). After the catheter has been inserted, the stylet is removed (see column 4, last four lines), and cardioplegia is administered.

It will be appreciated that the balloon of Briscoe is not adapted to be fixed in place when the flow of cardioplegia is halted. Briscoe's stylet 46 is only intended to be present during initial insertion of the catheter. Thereafter, the stylet is removed to enable cardioplegia to be administered, the cardioplegia also inflating the balloon.

When the flow of cardioplegia is halted, there is nothing to prevent the balloon from collapsing, contrary to the presently claimed invention.

An inherent structural difference between Briscoe and the presently claimed invention is that Briscoe's plug blocks (rather than maintains) communication between the lumen inlet and the lumen outlet while the plug is in a position closing the balloon passages. That is of no consequence in Briscoe because the stylet is only present when inserting the catheter. However, in the presently claimed invention, it is important that the lumen inlet communicate with the lumen outlet while the valve is in both the open and closed positions.

In conclusion, nowhere does Briscoe disclose a valve (or passage opening/closing means) which can maintain fluid communication between the lumen inlet and lumen outlet while in both its open position and closed position (see the closed positions shown in Figs. 8 and 20 wherein the lumen inlet cannot communicate with the lumen outlet. Accordingly, it is submitted that claims 1 and 5 distinguish patentably over *Briscoe*.

In light of the foregoing, it is submitted that the application is in condition for allowance.

Respectfully submitted,

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